

IN THE UNITED STATES COURT OF FEDERAL CLAIMS

OFFICE OF SPECIAL MASTERS

JESSICA GOSS,

Petitioner,

v.

SECRETARY OF HEALTH
AND HUMAN SERVICES,

Respondent.

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No. 99-407V

Special Master Christian J. Moran

Filed: December 20, 2006

Judgement on the record; denial of
compensation; hepatitis B; myokymia;
autoimmune disorder.

Clifford J. Shoemaker, Shoemaker & Associates, Vienna, Virginia for petitioner
Glenn A. MacLeod, United States Dep't of Justice, Washington, D.C. for respondent

UNPUBLISHED DECISION¹

The petition alleges that Jessica Goss's receipt of the hepatitis B vaccine caused an adverse reaction. Petition, filed June 28, 1999. Although the petition does not identify the specific injury that Jessica suffered, it seeks compensation pursuant to the National Vaccine Injury Compensation Program ("the Program"). 42 U.S.C. §§ 300aa-1 et seq. Information submitted later suggests that Jessica suffers from, among other conditions, myokymia, a benign condition marked by brief spontaneous tetanic contractions of motor units or groups of muscle fibers.²

¹ Because this unpublished decision contains a reasoned explanation for the special master's action in this case, the special master intends to post it on the United States Court of Federal Claims's website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002).

Vaccine Rule 18(b) states that all decisions of the special masters will be made available to the public unless they contain trade secrets or commercial or financial information that is privileged and confidential, or medical or similar information whose disclosure would clearly be an unwarranted invasion of privacy. When such a decision or designated substantive order is filed, petitioner has 14 days to identify and to move to delete such information before the document's disclosure. If the special master, upon review, agrees that the identified material fits within the banned categories listed above, the special master shall delete such material from public access.

² DORLAND'S ILLUSTRATED MEDICAL DICTIONARY, 30th Ed., p.1214.

On November 13, 2006, Jessica filed a Motion for a Ruling on the Record. This motion is GRANTED. The Court finds that the information on the record does not show entitlement to an award under the Program. Petitioner's claim for compensation is hereby DENIED.

I. FACTS

Jessica Goss was born on June 7, 1985. Exhibit 17 at 47. Between her birth and her receipt of the hepatitis B vaccinations in 1996, she suffered from a variety of ailments, including neonatal jaundice (Exhibit 17 at 25); seizures (Exhibit 17 at 48-49); an abnormal EEG (Exhibit 17 at 41); persistent irritable bowel syndrome (Exhibit 10 at 11); staring spells (Exhibit 17 at 34); abdominal pain and diarrhea (Exhibit 17 at 25, Exhibit 22 at 145); and scoliosis (Exhibit 6 at 1). It is unclear, if or how, these illnesses relate to her condition post-vaccination. Petitioner's mother, Linda Goss, states "Jessica had normal childhood illnesses and was a healthy child until 1996 when she began receiving the Hepatitis B series." Exhibit 43 ¶ 7. In contrast, respondent notes, in its report, that "the treating physicians do not appear to consider Jessica's abundant medical history that preceded vaccination as a possible factor in her injury." Respondent's Report at 15.

As relevant to this case, Jessica received her first dose of the hepatitis B vaccine on July 9, 1996, during a well-child exam. Exhibit 1 at 1; Exhibit 22 at 1. In her mother's affidavit, drafted on June 13, 2006, Linda Goss states that after the first shot, Jessica "developed a twitch under her eye and started complaining of back pain." Exhibit 43 ¶ 8.

Jessica received her second shot approximately one month later on August 13, 1996. Exhibit 1 at 1. There is no mention of any twitch or pain at that doctor visit. Exhibit 2 at 1.

On February 7, 1997, Jessica saw Dr. Alan Moskowitz of the Center for Scoliosis and Spine Disorders, because Dr. Moskowitz previously diagnosed Jessica with mild (9 degree) idiopathic left thoracic scoliosis in July 1995. There is no suggestion that the vaccinations caused Jessica's scoliosis because the scoliosis was diagnosed before the vaccinations. Jessica also saw Dr. Moskowitz for follow up appointments on August 25, 1997 and March 6, 1998. See, generally, exhibit 6.

On March 31, 1997, Jessica saw Dr. Kieserman, her pediatrician, for complaints of a headache that started approximately two and a half weeks prior, a rash on her face and neck, and chest pain. She was treated with an inhaler and Erythromycin. Exhibit 2 at 2. Jessica's third hepatitis B vaccination, along with a diphtheria/tetanus vaccination, was given at a well-child exam on June 23, 1997. Exhibit 1 at 1.

Approximately one year later, at her March 6, 1998 visit with Dr. Moskowitz, Jessica complained of upper thoracic and right rib pain. Dr. Moskowitz recommended a bone scan. Exhibit 6 at 4. On the same day, Jessica's medical history noted intrascapular back pain that had persisted for about one year. *Id.*

On March 12, 1998, an exam by Dr. Kieserman revealed intermittent bilateral eyelid twitch that worsened with discussion and right mid-line T3-4 tenderness that improved with activity. Exhibit 2 at 3.

Jessica saw Dr. Philip Riback, a neurologist, on March 27, 1998. He examined her for increased eye-twitching and occasional oscillopsia in the right eye. Exhibit 3 at 1. Dr. Riback concluded that Jessica appeared to have a peripheral neuropathy, specifically an axonal neuropathy. He also noted the possibility that her condition was a demyelinating neuropathy, but qualified that it was less likely than an axonal neuropathy. Id. at 3.

In April 1998, Dr. James Storey, a neurophysiologist, conducted Jessica's electrodiagnostic study. He found no evidence of demyelinating polyneuropathy and stated that "consideration should be given to autoimmune disorders or hereditary neuropathies." Exhibit 16 at 29; Exhibit 22 at 123; Exhibit 30 at 57.

From April to September of 1998, Jessica continued to see Dr. Riback. He determined that she had "inflammatory polyneuropathy with both demyelinating and axonal component." Exhibit 30 at 42; Exhibit 22 at 114.

On October 6, 1998, Jessica saw Dr. Spencer Weig, a pediatric neurologist. Jessica's mother related to Dr. Weig that she believed that Jessica's symptoms were connected to the hepatitis B vaccinations. Exhibit 5 at 2. Dr. Weig determined that "[t]he etiology for the problems remains obscure." Exhibit 22 at 104; Exhibit 5 at 1.

In January of 1999, Jessica saw Dr. Richard Moxley III, the Director of the Neuromuscular Disease Center at Strong Memorial Hospital. Exhibit 10 at 1. Dr. Moxley suspected that Jessica had probable immune mediated myokymia and connective tissue disease. Id. at 3. Dr. Moxley stated that Jessica "may have produced antibodies in response to her hepatitis B vaccination or in response to some other challenge that have affected the function of central nervous system potassium channels." Id. at 2. Alternatively, Dr. Moxley suggested that Jessica may have developed antibodies to glutamic acid decarboxase. Id.

Jessica continued to see a variety of doctors including a psychologist (Exhibit 26 at 15), a psychiatrist (Exhibit 18 at 67), a gastroenterologist (Exhibit 20 at 1), an allergist/immunologist (Exhibit 22 at 40), a rheumatologist (Exhibit 30 at 7), an otolaryngologist (Exhibit 16 at 31), and an endocrinologist (Exhibit 16 at 24). She developed a series of other conditions including a fibromyalgia, secondary to her neuropathy myokymia and sleep deprivation. Exhibit 22 at 31. Jessica also developed amenorrhea and polycystic ovaries syndrome. Exhibit 16 at 11.

Eventually, Jessica started seeking treatment from medical personnel at the neurology department of the Albany Medical Center. Exhibit 27, 32 and 33. One of the doctors at that facility, Dr. Matthew Murnane, wrote a letter "To Whom It May Concern" expressing his opinion

that Jessica suffers from “an underlying immune-mediated polyneuropathy that was a sequela to her hepatitis B vaccine that she received as a young teenager.” Exhibit 35 at 1.

Jessica also submitted a “To Whom It May Concern” letter from her current primary care physician, Dr. Gary Griffith. Dr. Griffith states that Jessica has “a multitude of autoimmune phenomena as a result of receiving a Hepatitis B vaccine.” Exhibit 34.

II. PROCEDURAL HISTORY

Joseph and Linda Goss, Jessica’s parents, filed this petition on her behalf on June 28, 1999, when she was a minor. (In October 2003, when Jessica reached the age of majority, the caption of the case was changed to indicate that she was prosecuting the case. This change does not affect the merits of the case.) Jessica filed her medical records over the course of four years from 2002 to 2006. In support of her claim, she also filed two opinion letters from Dr. Gary Griffith and Dr. Matthew Murnane, which are discussed in more detail below. Exhibit 34 and Exhibit 35.

Respondent filed its report, pursuant to Vaccine Rule 4, on September 27, 2006. In its report, respondent asserted that the request for compensation should be denied. Respondent argued that Jessica did not offer “a reliable theory of vaccine causation demonstrated by objective medical research and by the specific medical facts of this case.” Respondent’s Report at 17. Jessica also did not offer a “reputable medical or scientific theory persuasively connecting the vaccine to the injury, nor has [she] shown a logical sequence of cause and effect between vaccination and injury.” *Id.* Along with its report, respondent also filed two expert reports from Dr. Michael Cohen and Dr. Barry Bercu. Exhibit A and Exhibit C. Additionally, on October 16, 2006, respondent filed medical literature in support of its position. Exhibits E-V.

On November 13, 2006, Jessica submitted a motion seeking a ruling on the record and an accompanying proposed “Entitlement Decision.” Petitioner’s Motion for Judgment on the Record, filed November 13, 2006, at 1. In her motion, Jessica states that she “does not feel that she can prove causation as she cannot find an expert to support causation in her case.” *Id.* Respondent filed its response on November 28, 2006.

III. ANALYSIS

To receive compensation condition under the Program, Jessica must prove either: (1) that she suffered a “Table Injury”—that is, an injury falling within the Vaccine Injury Table—corresponding to one of her vaccinations, or (2) that she suffered an injury that was actually caused by a vaccine. See 42 U.S.C. §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1); Capizzano v. Sec’y of Health and Human Servs., 440 F.3d 1317, 1320 (Fed. Cir. 2006). Here, Jessica does not claim that she suffered a table injury. Thus, she must prove causation in fact.

A petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. 42 U.S.C. § 300aa-13(a)(1). In determining whether a petitioner is entitled to compensation, the special master shall consider all material contained in the record. 42 U.S.C. § 300aa-13(b)(1). This universe necessarily includes "any . . . conclusion, [or] medical judgment . . . which is contained in the record regarding . . . causation . . . of the petitioner's illness." 42 U.S.C. § 300aa-13(b)(1)(A).

The records are sufficiently developed that a decision made be made as to whether Jessica is entitled to a Program award. See 42 U.S. C. § 300aa-12(d)(3)(B)(v); Vaccine Rule 8(b).

To prove causation in fact, a petitioner must establish at least three elements. The petitioner's

burden is to show by preponderant evidence that the vaccination brought about [the] injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health and Human Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required; a preponderance of the evidence suffices. Bunting v. Sec'y of Health and Human Servs., 931 F.2d 867, 873 (Fed. Cir. 1991).

The records do not support a judgment in favor of Jessica because she has failed to establish any of the three prongs required by Althen. Jessica's absence of proof is most readily apparent with regard to the third prong – "proximate temporal relationship between vaccination and injury."

Medical records indicate that Jessica first experienced headaches and eye twitching more than six months after receiving the first two doses of hepatitis B. She received the first two doses in July and August 1996. Exhibit 1 at 1.

Headaches and eye twitching began in March 1997, at the earliest. On the last day of March 1997, Jessica saw her pediatrician, Dr. Kieserman. She complained of a headache that started two and a half weeks earlier. She also complained about a rash on her face and neck and that her chest was hurting. Significantly, the records do not indicate that she complained about eye twitching. Exhibit 2 at 2.

It is likely that eye twitching began in early April 1997, after Jessica saw Dr. Kieserman on March 31, 1997. On October 6, 1998, Jessica was seen by Dr. Weig who reported that the eyelid twitching began approximately 18 months earlier (or April 6, 1997). Exhibit 22 at 103.

Although other reports given to Dr. Kieserman and Dr. Riback estimate that the eyelid twitching began in mid-March 1997, these reports are estimates. See exhibit 2 at 3; exhibit 22 at 120. Due to the fact that these reports were describing events occurring about one year older, they are less persuasive than the notes from the March 31, 1997 visit to Dr. Kieserman, which does not refer to any eye twitching. Thus, a preponderance of the evidence demonstrates that the eye twitching began in April 1997. However, whether the eye twitching began in April 1997 or March 1997 is a distinction without a meaningful difference because even an onset date in March means that more than six months elapsed after Jessica received her second hepatitis B vaccine in August 1996. Of course, because the third hepatitis B vaccine was administered in June, 1997 (exhibit 1 at 1), it could not have caused the eyelid twitching.

Jessica failed to submit any evidence concerning the appropriate temporal relationship between the vaccination and the onset of her signs and symptoms. This lack of evidence, by itself, indicates that she has failed to establish one of the factors required by Althen. The Federal Circuit has stressed the importance of the temporal relationship by stating “without some evidence of temporal linkage, the vaccination might receive blame for events that occur weeks, months, or years outside of the time in which scientific or epidemiological evidence would expect an onset of harm.” Pafford v. Sec’y of Health & Human Servs., 451 F.3d 1352, 1358 (Fed. Cir. 2006), rehearing and rehearing en banc denied, No. 05-5106, 2006 U.S. App. Lexis 28907 (Fed. Cir. Oct. 24, 2006). Having the symptoms follow the vaccination is not sufficient to establish an appropriate temporal sequence. Abbott v. Sec’y of Health and Human Servs., 27 Fed. Cl. 792 (1993); Fricano v. Sec’y of Health and Human Servs., 22 Cl. Ct. 796, 800 (1991).

While a finding that Jessica failed to meet her burden of proof regarding the third Althen factor suffices as a basis for a judgment against her, for the sake of completeness, the first two Althen factors are analyzed below. For each of these factors, Jessica has also failed to meet her burden of proof.

By medical records or by medical opinion, Jessica has failed to establish the first prong of Althen – “a medical theory causally connecting the vaccination and the injury.” As mentioned, she presented two opinion letters from Dr. Griffith and Dr. Murnane. Dr. Griffith’s letter states that Jessica “suffers from a multitude of autoimmune phenomena as a result of receiving a Hepatitis B vaccine.” Exhibit 34 at 1. He continues to describe Jessica’s condition but fails to offer any theory connecting her injuries to the receipt of the vaccine.

Similarly, Dr. Murnane states that Jessica has “diffuse myokymia which is felt related to an underlying immune mediated polyneuropathy that was a sequela to her hepatitis B vaccine that she received as a young teenager.” Exhibit 35 at 1. He goes on to state that “[t]his has been the impression of the several neurologists who have seen her previous[ly], namely Drs. Riback and Weig, and I agree with their assessment.” *Id.* Despite this assertion, the letter does not contain any theory which details how the vaccine caused her injuries. Moreover, as discussed below, the evidence from Dr. Weig and Dr. Riback is actually much more circumscribed.

Dr. Weig stated the following: “Parents have noted a temporal association between Jessica’s symptoms and the hepatitis B immunization series. She had received the first two immunizations in the summer of 1996 prior to the onset of her symptoms several months later. She then received a booster in the summer of 1997. Following the booster, the neurologic symptoms increased quite a bit.” Exhibit 22 at 104. This appears to be the strongest statement from Dr. Weig connecting the vaccination with Jessica’s symptoms. Given that it is only a recitation of Jessica’s parents’ impressions, it does not support Dr. Murnane’s statement that Dr. Weig shares his conclusion that the hepatitis B vaccine caused Jessica’s problems. Indeed, Dr. Weig’s own statement is that “[t]he etiology for the problems remains obscure.” Exhibit 22 at 104; Exhibit 5 at 1. Because Dr. Weig does not identify the hepatitis B vaccinations as the cause of Jessica’s problems, he does not offer any theory explaining causation.

Additionally, Dr. Riback’s records do not appear to contain any mention of the hepatitis B vaccination or its connection with Jessica’s injuries. See, generally, Exhibit 3. The basis for Dr. Murnane’s statement that Dr. Riback agrees with Dr. Murnane’s opinion that the hepatitis B vaccine caused Jessica’s polyneuropathy is unclear. This lack of substantiation lessens the reliability of Dr. Murnane’s opinion.

Viewed in the light most favorable to Jessica, Dr. Griffith and Dr. Murnane stated that the hepatitis B vaccine caused Jessica’s condition. However, these statements do not satisfy her burden of proof. Their opinions do not express a “medical theory.” Rather, these statements are conclusions that lack a theory explaining how the hepatitis B vaccine caused Jessica’s condition. Neither Dr. Griffith nor Dr. Murnane explain why the first signs and symptoms of her myokymia began more than six months after the vaccinations. Without any reasoning explaining how Dr. Griffith and Dr. Murnane came to their conclusions, assessing the accuracy of their statement is very difficult, if not impossible. See Perreira v. Sec’y of Health & Human Servs., 33 F.3d 1375, 1377 n.6 (Fed. Cir.1994) (“An expert opinion is no better than the soundness of the reasons supporting it.”). Therefore, these statements are entitled to little weight.

Other statements from treating physicians also do not assist Jessica in meeting her burden of providing a medical theory linking the vaccine to the injury. Dr. Clifford Passen wrote to Dr. Kiserman that Jessica “seems to have had a reaction to a series of Hepatitis B vaccinations . . . which have apparently result[ed] in diffuse autoimmune disorders.” Exhibit 18 at 67. This statement, while linking Jessica’s injuries to the vaccinations, does not offer a medical theory explaining how the vaccinations caused the injuries. Therefore, it too is insufficient under Althen.

Dr. Moxley stated that “it is conceivable that [Jessica] may have produced antibodies in response to her hepatitis B vaccination or in response to some other challenge that have affected the function of central nervous system potassium channels.” Exhibit 10 at 2. While Dr. Moxley states that it is a possibility, he alternatively offers that Jessica “may have developed antibodies to glutamic acid decarboxase.” *Id.* A “possibility”, however, cannot establish a medical theory. Van Epps v. Sec’y of Health and Human Servs., 26 Cl. Ct. 650, 654 (1992); Doe v. Sec’y of

Health and Human Servs., 19 Cl. Ct. 439, 450 (1990) (“an assertion that something is ‘highly possible’ does not rise to the level necessary to establish causation by a preponderance of the evidence”); Snowbank Enter. v. United States, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation does not establish a probability); Duncan v. Sec’y of Heath and Human Servs., No. 90-3809V, 1997 WL 75429, at *4 (Fed. Cl. Spec. Mstr. Feb. 6, 1997) (“The court notes further that [petitioner's expert] is unwilling to state his opinion to a reasonable degree of ‘medical probability’ but as ‘a possibility’ only, a standard that cannot support a finding of a preponderance of evidence.”); Lacour v. Sec’y of Heath and Human Servs., No. 90-316V, 1991 WL 66579, at * 5 (Cl. Ct. Spec. Mstr. Apr. 15, 1991) (“Expert medical testimony which merely expresses the possibility – not the probability – of the occurrence of a compensable injury is insufficient, by itself, to substantiate the claim that such an injury occurred.”).

Furthermore, Jessica has failed to establish the second prong of Althen – a logical sequence of cause and effect. Again, because she did not present an expert opinion, her evidence must be found in the medical records.

The records explain that Jessica had a variety of ailments and injuries. It is unclear whether her troubles were caused by peripheral neuropathy or an immunologic process or myokymia. Exhibit 22 at 31; Exhibit 29 at 4; Exhibit 22 at 65. The medical records do not contain any statement, expressed with the requisite degree of certainty and clarity, that the hepatitis B vaccination caused the injuries.

In short, Jessica has failed to meet her burden of proving any of the factors required by Althen. Thus, compensation may not be awarded to her.

IV. CONCLUSION

For these reasons, petitioner’s claim for compensation is hereby DENIED. In the absence of a motion for review, the Clerk of the Court shall enter judgment dismissing the petition.

IT IS SO ORDERED.

S/ Christian J. Moran

Christian J. Moran
Special Master